

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Keith Anderson et al.

Application No.: To be assigned

Group Art Unit: To be assigned

Filed: January 10, 2001

Examiner: To be assigned

For: Transepithelial Delivery Of GLP-1 Derivatives

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

IN THE SPECIFICATION:

At page 1, after the title, insert

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of United States provisional application no. 60/177,002 filed on January 19, 2000 and Danish application no. 2000 00030 filed on January 11, 2000, the contents of which are fully incorporated herein by reference.--

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A pulmonary liquid or dry formulation comprising a GLP-1 compound [whereto is attached] wherein a lipophilic substituent is optionally attached via a spacer.

Claim 4, line 1, delete "any one of claims 1-3" and insert --claim 1--.

Claim 5, line 1, delete "any one of claims 1-4" and insert --claim 1--.

Claim 6, line 1, delete "any one of claims 1-5" and insert --claim 1--.

8. (Amended) The pulmonary formulation of claim 1 wherein said GLP-1 compound [whereto is attached] wherein a lipophilic substituent is attached via a spacer is Arg³⁴Lys²⁶(N⁶-(γ -glutamyl(N⁶-hexadecanoyl))-GLP-1(7-37)-OH, Arg¹⁸, Leu²⁰, Gln³⁴, Lys³³ (N⁶-(γ -aminobutyroyl(N⁶-hexadecanoyl))) Exendin-4-(7-45)-NH₂ or Arg³³, Leu²⁰, Gln³⁴, Lys¹⁸ (N⁶-(γ -aminobutyroyl(N⁶-hexadecanoyl))) Exendin-4-(7-45)-NH₂.

Claim 9, line 1, delete "anyone of claims 1-8" and insert --claim 1--.

10. (Amended) A pulmonary delivery device comprising a GLP-1 compound [whereto is attached] wherein a lipophilic substituent is optionally attached via a spacer.

11. (Amended) A method for preparing a pulmonary liquid or dry formulation for use in a pulmonary device, said formulation comprising a GLP-1 compound [whereto is attached] wherein a lipophilic substituent is optionally attached via a spacer.

12. (Amended) A method for preparing a pulmonary delivery device, said device comprising a GLP-1 compound [whereto is attached] wherein a lipophilic substituent is optionally attached via a spacer.

13. (Amended) A method of reducing blood glucose levels, treating diabetes type I, diabetes type II, or obesity, or inhibiting gastric acid secretion, or inhibiting apoptosis of β -cells, comprising administering to a patient in need thereof an effective amount of a GLP-1 compound [whereto is attached] wherein a lipophilic substituent is optionally attached via a

spacer by inhalation so as to deposit said GLP-1 compound[whereto is attached a lipophilic substituent optionally via a spacer] in the lungs of the patient.

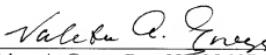
Please cancel claims 14 and 15.

REMARKS

Claims 14-15 have been canceled without prejudice or disclaimer. Therefore, claims 1-13 are pending in the present application.

This amendment is submitted to correct improper multiple dependent claims and grammar. No new matter added, and entry of the amendment is respectfully requested.

Respectfully submitted,



Valeta A. Gregg, Reg. No. 35,127
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Date: January 10, 2001